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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,934	08/21/2003	Kaneyoshi Kato	2444 US2P	8254

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EXAMINER

HABTE, KAHSAY

ART UNIT PAPER NUMBER

1624

DATE MAILED: 08/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/645,934

Applicant(s)

KATO ET AL.

Examiner

Kahsay Habte, Ph. D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-39 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

5.0.0

DETAILED ACTION

1. Claims 1-39 are pending in this application.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-21 (in part), 24-25 (in part), 29 (in part), 37 (in part) and 39 (in part), drawn to compounds where the variables **A** and **B** form a quinoline ring, **Y** = -CH₂-CH₂- or CH₂; and **R**¹ = **R**² = methyl or ethyl, classified in class 546, subclass 152.
 - II. Claims 1-16 (in part), 18-24 (in part), 26-29 (in part), 37 (in part) and 39 (in part), drawn to compounds where the variables **A** = phenyl; **B** = cyclohexyl; **Y** = -CH₂-CH₂- or CH₂; and **NR**¹ **R**² form a piperidine ring, classified in class 546, subclass 184.
 - III. Claims 1-16 (in part), 18-24 (in part), 26-29 (in part), 37 (in part) and 39 (in part), drawn to compounds where the variables **A** = phenyl; **B** = cyclohexyl; **Y** = -CH₂-CH₂- or CH₂; and **NR**¹**R**² form a pyrrolidine ring, classified in class 548, subclass 400.
 - IV. Claims 1-29 (in part), 31-34 (in part), 37 (in part) and 39 (in part), drawn to compounds where the variables **A** = phenyl, **B** = cyclohexyl, **Y** = -CH₂-CH₂- or CH₂; and **R**¹ = **R**² = methyl or ethyl, classified in class 564, subclass 378.

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- V. Claims 1-29 (in part), 30, 31-34 (in part), 37 (in part) and 39 (in part), drawn to others, classified in class 544, 546, 548, 549 and 564, subclass various.
- VI. Claims 35-36 and 38, drawn to method of use, classified in class 514, subclass various.

The inventions are distinct, each from the other because of the following reasons:

Groups I-V are directed to structurally dissimilar compounds such that the variable core created by the varying definitions of **A**, **B**, **Y**, **R¹** and **R²** in the formula do not belong to the same recognized class of chemical compounds in the art, and references anticipating one invention, would not render obvious the others. Group I is drawn to quinoline core structure (bicyclic ring with one nitrogen, see Examples 85-87) and is different from Groups II-V, since the Groups II-V do not have this core structure. Group II is drawn to bicyclic non-heterocyclic core structure (**A** = phenyl; **B** = cyclohexyl) where **NR¹R²** forms a piperidine ring (see Example 40) and is different from Groups I and III-V. Group III is drawn to bicyclic non-heterocyclic core structure (**A** = phenyl; **B** = cyclohexyl) where **NR¹R²** form a pyrrolidine ring (see Example 39) and is different from Groups I-II and IV-V. Group IV is drawn to bicyclic non-heterocyclic ring and is different from Groups I-III and V. Group V is drawn to others (e.g. different heterocyclic rings fused to the benzo ring; **NR¹R²** forms piperazines, etc.) and is different from Groups I-IV. Inventions I-V and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially

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different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case quinolines are used as PDE4 inhibitors in the treatment of rheumatoid arthritis that is materially different process.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

In addition, applicants have to elect a single disclosed species. If applicants elect Group IV, further restriction may be required.

Advisory Rejoinder

3. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

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In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

A telephone call was made to Mr. Mark Chao on July 15, 2005 to request an oral election to the above restriction requirement, but did not result in an election being made.

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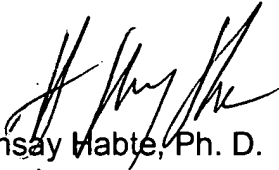
Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Conclusion

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kahsay Habte, Ph. D. whose telephone number is (571)-272-0667. The examiner can normally be reached on M-F (9.00- 5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Kahsay Habte, Ph. D.
Examiner
Art Unit 1624

8/1/2005